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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/620,840	07/21/2000	Lance E. Steward	D-2885	4487

33197 7590 03/12/2004

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/620,840

Applicant(s)

STEWART ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-71 is/are pending in the application.
- 4a) Of the above claim(s) 70 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 65-67 is/are allowed.
- 6) ☒ Claim(s) 68, 69 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 65-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1/12/04 & 2/28/03
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 12/29/03
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/04 has been entered.

2. Newly submitted claim 70 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Applicant's elected with traverse Group I for serotype A, as it relates to only generic SEQ ID NO: 2, in Paper No. 21, which was made FINAL in Paper NO: 22. In contrast, none of the recited SEQ ID NOs in claim 70 conform to elected SEQ ID NO: 2.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 70 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claim 70 drawn to an invention nonelected with traverse in Paper No. 21. A complete reply to the final rejection from Paper No: 22 must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. The rejection of claims 44-45, 47-53, 55-56 & 58-64 under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn due to the cancellation of these claims.
4. The rejection of claims 44-45, 47-53, 55-56 & 58-64 under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (US Patent 5,939,070) is withdrawn due to the cancellation of these claims.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Applicant's arguments filed 1/12/04 have been fully considered but they are not deemed to be persuasive.
7. Claims 65-67 are allowed.
8. Claims 68-69 & 71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific modified BoNT/A neurotoxin proteins with a definable sequence change and recited definable and assayable function, does not reasonably provide enablement for any structurally undefined additional sequences "in part" that do not reasonably possess the recited function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the

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invention commensurate in scope with these claims, for the reasons made of record in Paper NOs. 17 (mailed 12/31/02) & 22 (mailed 11/10/03), and as follows.

Pages 12-13 & 26 of the specification describe leucine-based motifs, in which additional leucine-based motifs putatively increase the biological half-life of BoTN/A. In contrast, addition of only “part of a [7 amino acid] leucine based motif” would not reasonably have such function, because the specification alternatively describes this 7 amino acid sequence as the minimal critical amino acid residues necessary to increase biological half-life of neurotoxins. Thus, one of skill in the art at the time of filing Applicants’ invention would not know how to make and use such modified BoTN/A molecules that have increased biological half-life without requiring undue experimentation to determine such; consistent with the teachings of Rudinger previously made of record.

9. Claims 68-69 & 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is ambiguous whether an “additional” leucine based motif “is added” to the claimed BoTN/A molecule, which alternatively still contains its naturally-occurring leucine based motif.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.

March 11, 2004

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